REMARKS

Reconsideration in view of the following remarks is respectfully requested. The Specification has been amended to correct the status of all priority applications and formatting of the Abstract. The Specification has also been amended to correct line 18 on page 72. Furthermore, the Title has been amended, as requested by the Examiner to clearly indicate the claimed invention which is directed to a product. Claims 54-79 and 81 have been canceled. Consequently, claims 80 and 82 are currently under consideration.

35 U.S.C. § 112, Second Paragraph

Claims 80 and 82 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite as failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action provides that:

> "Claim 80 is vague and indefinite for recitation of "protection protein", the intended metes and bounds of the protein is not defined. Is a ricin protein intended? The term "derived' in claim 80 is a relative term, with renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant case, the definition of derivation has many meaning, therefore, the claim is considered as indefinite. In addition the intended metes and bounds of the protein that is "derived" from a "polyimmunoglobulin receptor" is not defined. Moreover, the intended polyimmunoglobulin receptor is not defined. This affects claims 82."
>
> "Claim 82 is vague and indefinite for recitation of "plant produced", what is the intended plant. Is cacti intended?"
>
> "Claim 82 is rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP §2172.01. The omitted steps are: transformation, types of plant i.e., transgenic or non, the conditions that would permit the production of antibody should be stated."

Claim 80

Applicants disagree that the recitation of "protection protein", "derived", and "polyimmunoglobulin receptor" in claim 80 is vague. The specification clearly describes the scope of the terms.

On page 7, lines 3-8, the protection proteins are described as giving "the immunoglobulins containing these proteins useful properties including resistance to chemical and enzymatic degradation, and resistance to denaturation." Thus, the specification clearly provides what type of protein is intended, i.e., a protein that imparts to immunoglobulins they are associated with, enhanced resistance to various environmental conditions.

On page 22, lines 23-27, it is stated that the protection protein has an "amino acid sequence substantially corresponding to or analogous to at least a portion of residues 1 to 627 of the amino acid residue sequence of the rabbit polyimmunoglobulin receptor. Analogous regions between rabbit, rat, bovine, and human polyimmunoglobulin receptors are also provided in Table 1. Thus, the specification does provide a standard for ascertaining the requisite degree of derivation, i.e., derivation from an amino acid sequence substantially corresponding to or analogous to at least a portion of residues 1 to 627 of the amino acid residue sequence of the rabbit polyimmunoglobulin receptor.

Furthermore, on page 23, lines 10-17, the specification describes that the polyimmunoglobulin receptor (pIgR) from any species may be used since the protection proteins contain an amino acid sequence analogous to at least a portion of amino acids 1-627 of the rabbit pIgR, and examples of these analogous regions are listed in Table 1. Accordingly, Applicants submit that they are entitled to claim a generic polyimmunoglobulin receptor, and that the intended pIgR does not need to be identified.

Claim 82

Applicants disagree that the recitation of "plant produced" is indefinite. In the Examples, immunoglobulin and a protection protein was co-expressed in alfalfa, tomato, tobacco, and

Arabidopsis plants. Again, Applicants submit that an intended plant need not be identified, and that they are entitled to a generic "plant" because more than a single plant species is described.

Furthermore, Applicants disagree that essential steps have been omitted from the claim. Claim 82 is an immunoglobulin claim, not a method claim, nor a product-by-process claim. Thus, it is not necessary for steps such as plant transformation to be recited.

Statutory Double Patenting Rejection

Claims 80 and 82 stand rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 12, 13, and 29 of prior U.S. Patent No. 6,303,341 B1 ('341 patent).

The standard for determining whether a statutory basis for a double patenting rejection under 35 U.S.C. § 101 exists is whether the same invention is being claimed twice, wherein "same invention" means identical subject matter. *See* MPEP 804-IIA. A reliable test for double patenting under 35 U.S C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim of the patent. *See* MPEP 804-IIA (citing *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

In this application, claims 80 and 82 are not claiming the "same invention" as claims 1, 12, 13, and 29 of the '341 patent since claims 80 and 82 could be literally infringed without literally infringing the '341 patent claims. For example, claim 1 of the '341 patent (from which claims 12, 13, and 29 depend) recites that the "protection protein" is associated with an immunoglobulin derived heavy chain", whereas claims 80 and 82 do not. Thus, claims 80 and 82 could be literally infringed by an antibody in which the protection protein is associated with an antibody chain other than an antibody heavy chain, whereas claims 1, 12, 13, and 29 of the '341 patent would not.

Thus, claims 80 and 82 of this application and claims 1, 12, 13, and 29 of the '341 patent do not claim the "same invention", and the rejection under 35 U.S.C. § 101 is improper. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

The following claims stand rejected under 35 U.S.C. § 102(b): A) claims 80 and 82 as being anticipated by Lehner et al. (WO 88/06455); B) claim 80 as being anticipated by Lehner et al. (U.S. 4,594,244); and C) claim 80 as being anticipated by Schlom.

Applicants submit that the claim(s) under each Section 102 rejection are not anticipated. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See* MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

As further elucidated below, none of the cited art describes or suggests a protection protein derived from a polyimmunoglobulin receptor.

Lehner et al. (WO 88/06455)

Lehner et al. ('455 patent) teaches an antibody specific for S. sobrinus serotype d and methods for making the antibody. The S. sobrinus serotype d antibody, in comparison to antibody raised against S. mutans serotype c, are cross-reactive with most other S. sobrinus/S. mutans serotypes found in the oral cavity. In use, the antibodies are topically applied to prevent dental carries. No where in the reference do Lehner et al. describe a protection protein derived from a polyimmunoglobulin receptor.

Based on the foregoing, the '455 patent does not describe a limitation of claims 80 and 82, specifically, a protection protein derived from a pIgR. Consequently, the requirements under 35 U.S.C. § 102(b) have not been met, and withdrawal of the rejection is respectfully requested.

Lehner et al. (U.S. 4,594,244)

Lehner et al. ('244 patent) describe an antigenic material useful for making an anticarries vaccine. The antigenic material is obtained from antigen I/II isolated from S. mutans. The vaccine prepared from this antigenic material is then administered parenterally or topically to the gums.

Similar to the '455 patent, the '244 patent does not describe all the elements of claim 80, specifically, a protection protein derived from a polyimmunoglobulin receptor.

Withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

Schlom

Schlom teaches a monoclonal antibody for treating gastrointestinal cancer. The antibody may be conjugated to a label that allows detection of the tumor, or to a therapeutic agent. Conjugation to a protein, particularly a protein derived from a pIgR, that "protects" it from degradation and denaturation is not described.

Thus, the cited reference does not teach or suggest all the claim limitations under U.S.C. § 102(b). Accordingly, withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102(e)

Claim 80 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Lehner et al. 5,854,402). Specifically, the Office Action provides that:

> "The claims and teaching of the above cited patent meets the broad limitations of the claimed invention (see claim 1). Applicants are reminded that antibodies are capable of long range of binding. The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claims."

Applicants disagree that claim 80 is anticipated by Lehner et al. ('402 patent). The '402 patent is a continuation application of WO 88/06455, and thus contains the same specification. As discussed above, WO 88/06455 does not teach a protection protein derived from a polyimmunoglobulin receptor. Because a limitation of the claims is missing, a rejection under 35 U.S.C. § 102(e) is improper. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claim 82 stands rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Lehner et al. (WO 88/06455), in view of Hiatt et al. (U.S. Patent No. 5,202,422). Specifically, the Office Action provides that:

> "Claim 82 is directed in producing antibodies in plants. Lehner et al. as stated above taught the immunoglobulin (see claims) and Hiatt et al. taught a method of producing immunoglobulin in plants (see claims 5). Hence, one of ordinary skill in the art would have been motivated to generate antibodies taught by Lehner et al. (WO 88/06455), by utilizing the method of Hiatt et al. (U.S. Patent No. 5,202,422, 4/13/1993) in plants to be used in induction of immune response or diagnostic assay. The ordinary skill in the art would not have anticipated any unexpected result. Hence, the invention as a whole is considered to be prima facie obvious absent unexpected results."

Applicants respectfully remind the Examiner that in order to properly establish a *prima facie* case of obviousness, three basic criteria must be met, one of which the prior art reference (or references combined) must teach or suggest all claim limitations. *See* MPEP 2143.

As discussed above, Lehner et al. (WO 88/06455) does not describe an immunoglobulin having a protection protein derived from pIgR. Hiatt et al. does not cure this defect. Thus, the references combined do not meet the requirements of Section 103.

In view of the above arguments, Applicants respectfully submit that the grounds for rejection under 35 U.S.C. § 103 have clearly been overcome and request that the rejection be withdrawn.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to

charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 415142000302.

Respectfully submitted,

Dated: February 28, 2003 By: _____

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